

Attorney Docket: 24720
Serial No.: 10/022,799
Filed: December 20, 2001

AMENDMENT

In the Claims:

Please amend the claims as follows:

Claims 1-17: canceled.

18. (Currently amended) A method of making a micro and nano-particulate drug, the steps comprising:

providing a drug substance-surfactant mixture;
melting the mixture at a temperature above said mixture's melting temperature
such that a clear mixture is formed;
and cooling the mixture continuously under high shear to approximately room temperature,
wherein a non-crystalline substance forms or crystals precipitate coated with said surfactant during crystallization.

19. (Original) The method of claim 18, wherein said mixture is melted below the decomposition temperature of said drug substance.

20. (Original) The method of claim 18, wherein said non-crystalline substance is flowable.

21. Canceled.

22. (Original) The method of claim 18, wherein said drug substance is selected from the group consisting of: analgesics, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, immunosuppressants, antithyroid agents, antiviral agents, anxiolytic sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, cardiac inotropic agents, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, sex hormones, anti-allergic agents, stimulants and anoretics, sympathomimetics, thyroid agents, vasodilators, xanthines, and mixtures thereof.

23. (Original) The method of claim 18, wherein said surfactant is an organic excipient.

Attorney Docket: 24720
Serial No.: 10/022,799
Filed: December 20, 2001

24. (Original) The method of claim 23, wherein said excipient is selected from the group consisting of low molecular weight oligomers, natural products, gelatin, casein, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glyceryl monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, macrogol ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, and polyvinylpyrrolidone, polyvinyl alcohol, polyvinyl pyrrolidone, dextran, lecithin, polyvinylpyrrolidone, and organic solvent.

25. (Original) The method of claim 18, wherein said surfactant is nonionic or anionic.

26. (Original) The method of claim 18, wherein said drug is used in a pharmaceutically acceptable carrier.

27. (Original) The method of claim 26, wherein said pharmaceutically acceptable carrier is selected from the group consisting of diluents, binders, adhesives, lubricants, plasticizers, disintegrants, colorants, bulking substances, flavorings, sweeteners, buffers, and absorbents.

28. (Original) The method of claim 27, wherein said binder is selected from the group consisting of hydroxypropylmethylcellulose, ethylcellulose, povidone, acrylic, methacrylic acid co-polymers, pharmaceutical glaze, gums, and milk derivatives.

29. (New) The method of claim 18, wherein said surfactant-drug substance matrix has a melting point less than the decomposition temperature of said drug substance.

30. (New) The method of claim 18, wherein said crystals have a particle size of less than 5 microns.

31. (New) The method of claim 18, wherein said crystals have a particle size of less than 400 nm.

32. (New) The method of claim 18, wherein said crystals have a particle size of less than 250 nm.

33. (New) The method of claim 18, wherein an average particle size of said crystals is less than about 100 nm.

Attorney Docket: 24720
Serial No.: 10/022,799
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34. (New) The method of claim 18, wherein an average particle size of said crystals is less than about 250 nm.

35. (New) The method of claim 18, wherein at least 50% of said crystals have a particle size less than 5 microns.

36. (New) The method of claim 18, wherein at least 75% of said crystals have a particle size less than 5 microns.

37. (New) The method of claim 18, wherein said surfactant has a melting point at about room temperature.

38. (New) A micro or nano-particulate drug composition prepared according to the method of claim 18.